NO. 89-243

IN THE

Supreme Court of the United States

OCTOBER TERM, 1989

ELI LILLY AND COMPANY,

Petitioner

V.

MEDTRONIC, INC.,

Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF AMICUS CURIAE INTERMEDICS, INC., IN SUPPORT OF RESPONDENT

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QUESTION PRESENTED

Did the Court of Appeals for the Federal Circuit correctly construe 35 U.S.C. § 271(e)(1) to include an exemption for experimental use of medical devices?

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INTERESTS OF THE AMICUS CURIAE

This Brief is filed with written consent of the parties in accordance with Rule 37.3. Intermedics, Inc. ("Intermedics"), a Texas corporation, is a manufacturer of medical devices including pacemakers, implantable defibrillators, implantable prosthetic joints, and heart valves. Intermedics is a subsidiary of Sulzer Brothers Limited, a Swiss corporation. As a

manufacturer of medical devices and holder of patents on medical devices, Intermedics is a competitor of both the Petitioner, Eli Lilly and Company ("Lilly"), and the Respondent, Medtronic, Inc. ("Medtronic").

The determination of whether or not an experimental use exemption for medical devices is provided under 35 U.S.C. § 271(e)(1) has a direct impact on the conduct of Intermedics' business. Intermedics, as the holder of numerous medical device patents, would benefit by a reversal of the Appellate Court. As a competitor with third parties holding medical device patents which is engaged in preliminary testing of experimental devices, Intermedics would benefit by an affirmation. Intermedics believes the Court of Appeals for the Federal Circuit correctly interpreted 35 U.S.C. § 271(e)(1) and therefore files this Brief in Support of that interpretation, siding with the Respondent, Medtronic, albeit for different reasons.

SUMMARY OF ARGUMENT

Although this case concerns the construction of the patent laws which inevitably calls into play arguments relating to public policy, Intermedics believes that construction of 35 U.S.C. § 271(e)(1) should be based strictly upon principles of statutory construction. A part of 35 U.S.C. § 271(e) was found by the Court of Appeals for the Federal Circuit to be ambiguous. The ambiguity, if any, should be resolved by reference to parallel, unambiguous parts of 35 U.S.C. §§ 156 and 271 to produce a harmonious, symmetrical result.

Both parties, and many of the Amici who have come forward to aid this Court, have taken the position that 35 U.S.C. § 271(e) is unambiguous on its face, or that any ambiguity may be clearly and unequivocally resolved by reference to the legislative history. The Court of Appeals for the Federal Circuit did not agree. Although there are many aspects of this legislation that are clear, it was not clear to the Court of Appeals for the Federal Circuit whether an FDA experimental use exception to

infringement was extended to medical devices. Under these circumstances, a court should look for guidance to the actions of Congress in adopting the unambiguous, parallel portions of the statute and seek, as nearly as possible, to follow the pattern established thereby.

Sections 156 and 271(e)(1) unambiguously provided an extension of the patent term for drugs subject to regulatory delay (§ 156) and a corresponding experimental use exception (§ 271(e)(1)) for FDA testing of drugs. This legislation overruled the only relevant precedent, *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858 (Fed. Cir., 1984). Section 156 of the statute clearly provided an extension of patent term for medical devices, but it was not clear to the Court of Appeals for the Federal Circuit whether Section 271(e) (1) provided a corresponding FDA experimental use exception for medical devices. To resolve this perceived ambiguity, the Federal Circuit correctly followed the pattern set by Congress, and abandoned its own precedent in its entirety, finding it nonsensical to retain the *Roche* holding as precedent for all non-drug products.

Intermedics requests this Court to affirm the statutory construction of the Court of Appeals for the Federal Circuit which recognized the propriety of reconciling facially ambiguous statutory provisions to produce a harmonious, symmetrical result which is consistent with legislative intent.

ARGUMENT

I. The Scope of 35 U.S.C. § 271(e) is Unclear.

This is a case where the appellate court found the exact meaning of a statute to be unclear, and construed the statute in light of legislative intent. It has been argued by the parties and by numerous Amici that the statute "plainly" and "clearly" requires opposite results. Each side has argued that both the statute and its legislative history support their respective positions. The parties and various Amici have also argued that the possible effects of different interpretations on industry,

innovation and the public support their respective views. This Amicus adopts *in arguendo* that the appellate court correctly concluded that the statute is ambiguous. It cannot be said that medical devices are clearly and unequivocally included or excluded from the scope of 35 U.S.C. § 271(e).

Nevertheless, because a case has been brought to the courts for adjudication, the courts must adopt one interpretation or the other. This is the function of the courts, and it is not judicial legislation, although it will shape the law. To choose one interpretation is as much of an exercise of the judicial role as to choose the other. The choice, however, should be made on principles which can be reliably followed in other similar cases.

II. In Interpreting the Statute, the Court Should be Guided by the Action of Congress.

Congress speaks most clearly through its actions. It is impossible for a court or a litigant to poll a legislature, long after it has dissolved, for its interpretation of the meaning of a statute. Statements by individual legislators are of little assistance, for the opinions and sentiments of one cannot reasonably be attributed to all. To the extent a legislature has a unified intent, it is expressed in the action of the majority in adopting particular legislation, coupled with the corresponding action of the executive branch. To interpret statutes, a court should direct its attention, as much as possible, to the action of Congress in the unambiguous, parallel portions of the legislation. That is precisely what the Court of Appeals for the Federal Circuit has done in this case.

35 U.S.C. § 271(e)(1) was enacted in response to the decision by the Court of Appeals for the Federal Circuit in *Roche*. In that case, the Federal Circuit was asked to find that preliminary FDA testing was within the judicially created experimental use exemption from infringement. The Federal Circuit refused to do so. Later, Congress overruled the *Roche*

decision. On its facts, therefore, *Roche* has no further precedential value.

In overruling *Roche*, Congress clearly created an FDA experimental use exception for drugs under 35 U.S.C. § 271(e). At the same time, Congress provided an extension of the patent term for drugs which became 35 U.S.C. § 156. This is the undisputed, unambiguous action of Congress, an action which abolished the precedential value of *Roche*. In 35 U.S.C. § 156, Congress also unequivocally extended the patent term for medical devices. The scope of 35 U.S.C. § 271(e), which unequivocally provided the experimental use exception for drugs, does not clearly include or exclude medical devices, and the Court must provide an interpretation.

The methodology for interpretation adopted by the Federal Circuit offers the greatest potential for predictability and precision in the interpretation of statutes. The Federal Circuit turned back to the statute itself, perceived that Congress, in return for an FDA experimental use exception, had granted drug manufacturers a patent term extension and that Congress had granted device manufacturers a patent term extension but may or may not have imposed, in return, an FDA experimental use exception. The Federal Circuit resolved the ambiguity it found by treating the action of Congress in the handling of drugs as the best evidence available for the interpretation of the statute. Under the Federal Circuit's interpretation, drugs and devices are treated in the same way. Such an interpretation harmonizes the two sections regarding the treatment of patented inventions subject to regulatory delays, is consistent with congressional intent to overrule the *Roche* decision and is a proper exercise of judicial authority in statutory interpretation. *Federal Power Commission v. Panhandle Eastern Pipe Line Company*, 337 U.S. 498, 514; 69 S. Ct. 1251, 1260 (1949). This interpretation also results in consistent interpretation of the term "patented invention" throughout 35 U.S.C. § 271.

CONCLUSION

The Court of Appeals for the Federal Circuit correctly resolved the ambiguities in 35 U.S.C. § 271(e) so that the parallel portions of the statute would be consistent. The Federal Circuit's principled application of a doctrine of statutory interpretation should be affirmed.

Respectfully submitted,

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